

REMARKS

The Examiner is thanked for the due consideration given the application. This amendment is being filed concurrent with a Request for Continued Examination.

Claims 54-60, 64, 66, 68-75 and 114-116, 119, 120 and 121 are pending in the application. Claims 117 and 118 have been cancelled by this amendment. Claim 54 has been amended to clarify the invention being claimed, and finds support at page 6, lines 1-2 of the specification. Claims 119, 120 and 121 are new. Support for new claim 119 can be found in the specification at page 5, lines 21-22. Support for new claim 120 can be found in the specification at page 3, lines 18-19. Support for new claim 121 can be found, e.g., in Figure 3C.

No new matter is believed to be added to the application by this amendment.

Rejection Under 35 USC §112 Second Paragraph

Claims 115, 117 and 118 have been rejected under 35 USC §112, second paragraph as being indefinite. This rejection is respectfully traversed.

The Office Action asserts that the "mat" set forth in claim 115 has unclear antecedent basis in regards to claims 72 and 54. However, claim 54 has been amended to not recite a "mat". The antecedent basis of claim 115 is thus clarified.

Any issues in regards to claims 117 and 118 are mooted in light of their cancellation.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Art Rejections

Claims 54, 59, 60, 64, 66, 68, 72 and 116-118 have been rejected under 35 USC §102(b) as being anticipated by LI (U.S. Patent 5,594,057).

Claims 54-60, 64, 68, 71, 72, 74 and 114-118 have been rejected under 35 USC §102(b) as being anticipated by THIERFELDER et al. (U.S. Publication 2002/0028980).

Claim 69 has been rejected under 35 USC §103(a) as being unpatentable over LI in view of LOVUOLO (U.S. Publication 2002/0143234).

Claim 69 has been rejected under 35 USC §103(a) as being unpatentable over THIERFELDER et al. in view of LOVUOLO.

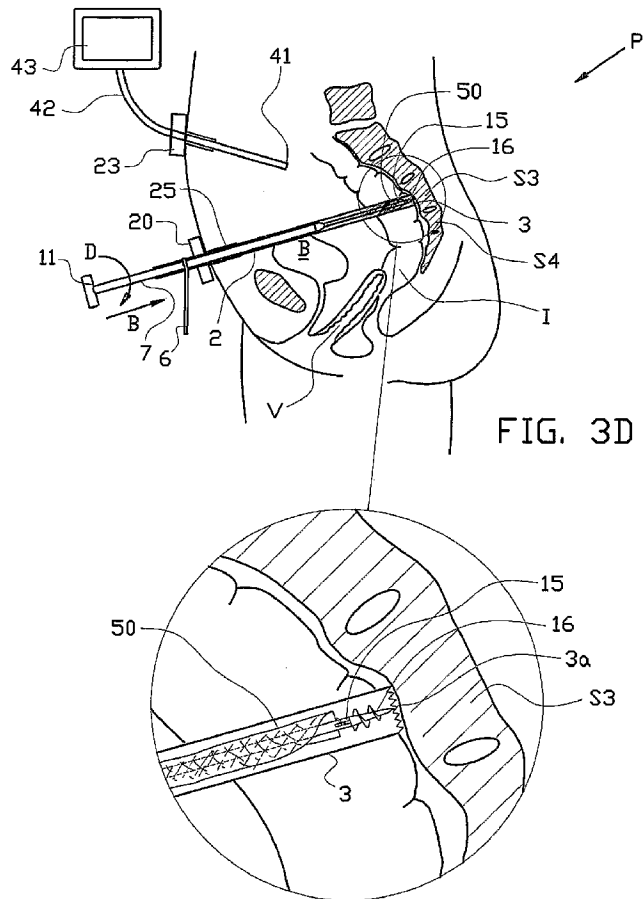
Claims 70 and 73 have been rejected under 35 USC §103(a) as being unpatentable over LI in view of WORTRICH (U.S. Patent 5,458,606).

Claims 70, 73 and 75 have been rejected under 35 USC §103(a) as being unpatentable over THIERFELDER et al. in view of WORTRICH.

These rejections are respectfully traversed.

The present invention pertains to an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum

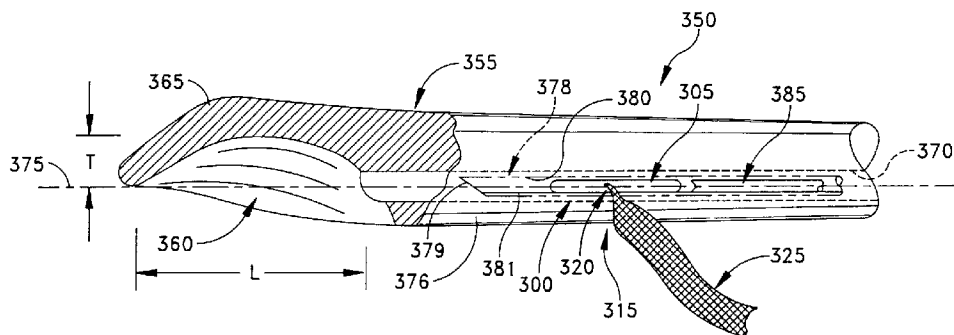
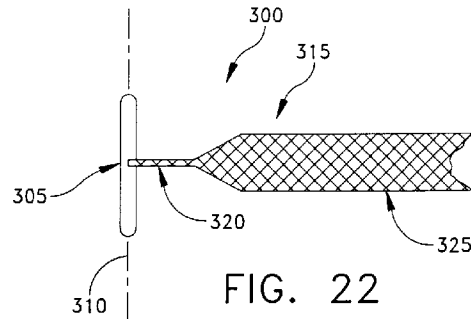
to her/his spine. The present invention is illustrated by way of example in Figure 3D of the application, which is reproduced below.



As is set forth in instant claim 54, the present invention includes a first tube, a second tube or rod having a length that at least equals the length of the first tube, which second tube or rod is provided with a distal end and includes an opposite proximal end, and at least one attachment device for penetrating into the spine provided with a distal end for attachment to the sacrum and a proximal end for attachment of an

end of a connector configured for connection to the patient's vaginal apex or uterus or rectum.

In rejecting the claims, the Office Action refers to Figures 22 and 23 of LI, which are reproduced below.



i. However, LI only explicitly discloses that the assembly can be used for attaching a connector to soft tissue, such as an internal organ, which connector can be connected to an appropriate bodily support structure, e.g., a skeletal structure, such as the pubic bone.

LI does not explicitly disclose an assembly for use in the attachment of a patient's vaginal apex or uterus or rectum to her/his **spine**.

ii. LI discloses a soft tissue suspension clip, a suspension clip assembly and an emplacement tool for the

suspension clip assembly. The emplacement tool 350 is used to deploy suspension clip assembly 330, as shown in Figure 22, so that at least a portion of the second, most proximal portion 325 of suspension strap 315 is disposed within the interior of the soft tissue when body 305 is disposed on the fat side of the soft tissue (column 16, lines 29-39).

In contrast, the assembly according to the present invention is used for attaching an attachment device, such as a bone screw, to the sacrum. To more clearly define the assembly of the inventions, claim 54 has been amended to read *"at least one attachment device configured for penetrating into the spine,"* which is supported at page 6, lines 1-2 of the specification.

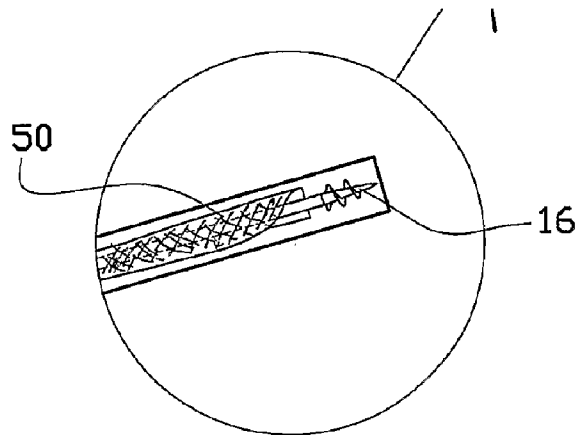
iii. Although LI discloses that the suspension strap 38 is fixed to bone B (in this case the pubic bone) using a pin P, the emplacement tools disclosed by LI and in particular emplacement tool 350, are neither intended, nor suitable for attaching an anchor or a pin to a skeletal structure, because the emplacement tools disclosed by LI are intended and suitable for attaching a suspension strap to soft tissue using a suspension clip having a structure for penetrating the soft tissue. In particular the Office Action seems to acknowledge that dependent claim 56 of the present invention, stating that *"the means for attachment is a bone screw"* is not anticipated by LI (claim 56 is not part of the anticipation rejection over LI).

iv. According to Figure 23 of LI, the first tube 355 is formed from a distal end 365. Adjacent to this distal end 365 is a pre-curved pocket 360. The first passage 370 extends through the first tube 355 and opens on the pre-curved pocket 360 as disclosed at column 16, lines 40-43. According to Figure 23 the opening of the passage 370 is arranged at a side of the pre-curved pocket facing away from the distal end of the first tube. Thus LI does not disclose a first passage from the distal to the proximal end of the first tube.

v. Furthermore, according to the Office Action, LI also discloses that part of the distal end of the second tube is narrowed for together with the first tube forming an accommodation space for said part of the means for connection (The Office Action refers to column 16, lines 55-61, and Figure 23 of LI).

LI discloses (Figures 22 and 23, and corresponding description starting at column 15, line 66 and ending on column 17, line 37) that the suspension strap 315 can pass from the body 305 disposed in bore 380 (second tube) to the region exterior of the shaft 378 (first tube). Thus according to LI, there is a passage which extends through the slot 381 in the bore 380 and the slot 381 in the housing 355, which slots are aligned to form the passage from the inside of the bore to the exterior of the housing.

In contrast, in the present invention a part of the distal end of the second tube is narrowed together with the first tube forming an accommodation space between the first and second tube for accommodating the connection means. In an embodiment, the connection means of the present invention is wrapped around the second (inner) tube so that it can completely be positioned within the first (outer) tube as, e.g., is shown in the enlargement of Figure 3C of the present application, which is reproduced below.



Thus LI explicitly teaches that a part of the suspension strap has to project out of the housing, and is not accommodated between the Shaft 378 and the housing 355, and thus teaches away from the present invention, in which the mat is completely situated within the outer tube.

In conclusion, claim 54 has been amended in order to more clearly describe the present invention, as being an apparatus having at least one attachment device for penetrating into the spine, to the sacrum, contrarily to the emplacement tool

(350) in Figure 23 of LI. Claim 54 has been amended to distinguish the present invention from a device for attaching a most proximal portion of a suspension strap with the interior of the soft tissue of an internal organ, as disclosed by LI.

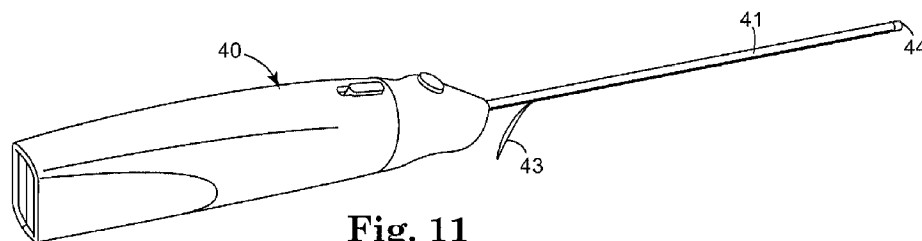
Moreover, in contrast the LI, the connector may be completely positioned within the first tube. See new claim 121.

The other applied art references do not address the deficiencies of LI discussed above.

LI alone or in combination thus does not anticipate or render *prima facie* obvious a claimed embodiment of the present invention.

Now consider THIERFELDER et al.

i. THIERFELDER et al. do mention the use of a manual screw driver or a powered screw driver that is sized and shaped to fit in the cannula of a trocar (as disclosed in paragraph [0139], as an example). However THIERFELDER et al. do not show or describe the combination of the surgical article 40 of Figure 11 and a trocar. This combination is suggested by the Office Action and not by THIERFELDER et al. Figure 11 of THIERFELDER et al. is reproduced below.



ii. The Office Action identifies reference number 40 in Figure 11 of THIERFELDER et al. as being the second rod. However, number 40 refers to the surgical article, and in particular to a handle of haft of the surgical article, which clearly is not intended to be movably accommodated in a first tube.

iii. The shaft 41 of THIERFELDER et al. could be interpreted as being a second rod (since it also is arranged for holding bone screw). However, there is neither an indication nor a suggestion that the shaft 41 can be movably accommodated in a first tube. And if a person skilled in the art would movably accommodate the shaft 41 of THIERFELDER et al. in a tube (such as a trocar), *quod non*, there is neither a hint nor a suggestion in THIERFELDER et al. that a distal end portion of the second tube or rod 41 is narrowed for together with the first tube forming an accommodation space for said part of the connector. Neither in the description, nor in the drawing figures in THIERFELDER et al., are the first and second rod specified as providing an accommodation space. This also is only suggested by the Office Action.

iv. In addition, the Office Action seems to suggest that the shaft 41 is accommodated into a trocar over such a length that the suture 43 is also inside the trocar. Again, this is suggested by the Office Action and not disclosed by THIERFELDER et al. In addition arranging the suture 43 inside

the trocar would be illogical, because in that case the suture would no longer be within the grasp of the surgeon.

The other applied art references do not address the deficiencies of THIERFELDER et al. discussed above.

THIERFELDER et al. alone or in combination thus does not anticipate or render *prima facie* obvious a claimed embodiment of the present invention.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

Prior art of record but not utilized is believed to be non-pertinent to the instant claims.

As no issues remain, the issuance of a Notice of Allowability is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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